



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: DEX-0087
Inventors: Recipon and Macina
Serial No.: 09/705,500
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Examiner: Canella, Karen A.
Group Art Unit: 1642

Title: A Novel Method of
Diagnosing, Monitoring, Staging,
Imaging and Treating Cancer

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Declaration by Dr. Nam Kim

I, Nam Kim, hereby declare:

1. I was awarded a Ph.D. degree in microbiology from the University of Toronto in 1993. After obtaining this degree, I worked at Geron Corporation in Menlo Park, California for eight years developing cancer diagnostic tests. In March of 2001 I joined diaDexus, Inc. where I am the Associate Director of Diagnostics.

2. As the Associate Director of Diagnostics for diaDexus, Inc. I am familiar with the teachings of the above-referenced patent application.

3. Since filing of the above-referenced patent application, the Diagnostics division at diaDexus Inc. has performed additional experiments confirming the ability of Lng108 protein to serve as a diagnostic marker for cancer.

4. In these experiments, serum samples from 35 normal, 25 breast cancer, 25 colon cancer, 25 lung cancer, and 25 prostate cancer patients (total of 160 samples) were analyzed by Lng108 pAb/pAb and mAb/pAb ELISA (pAb is polyclonal antibody, mAb is monoclonal antibody). Each set of cancer serum samples analyzed consisted of samples from patients with all stages and grades of the tumor. Normal serum samples were collected from apparently healthy

grades of the tumor. Normal serum samples were collected from apparently healthy individuals. Prior to analysis all samples were stored at -80 C.

5. Lng108 pAb/pAb and mAb/pAb ELISA was performed in accordance with a standard sandwich-ELISA protocol well known to those of skill in the art and outlined in the above-referenced patent application at page 12, line 24, through page 13, line 16. Polyclonal and monoclonal antibodies against Lng108 are raised in accordance with standard techniques well known to those skilled in the art.

6. Results from this ELISA are depicted in the attached scattergram. The scattergram shows nanograms of Lng108 protein per milliliter in serum of normals and patients with breast cancer, lung cancer, ovarian cancer and colon cancer as described in paragraph 4 herein. Mean Lng108 protein concentrations for each sample set were calculated and are shown at the bottom of the scattergram. The mean Lng108 protein concentration was increased at least 2-fold in serum samples of patients with every type of cancer examined as compared to normals. For most cancers, the mean was at least five times higher. Thus, these additional experiments confirm the teachings of the above-referenced patent application of Lng108 being a lung cancer diagnostic marker and a general cancer diagnostic marker.

I hereby declare that all statements herein of my own knowledge are true and that all statements made on information or belief are believed to be true; and further that these statements were made with the knowledge that willful statements and the like so made are punishable by fine or by imprisonment, or both, under §1001 of Title 18 of the United States code, and that such willful statements may jeopardize the validity of the application, any patent issuing there upon, or any patent to which this verified statement is directed.



Nam Kim, Ph.D.



Date

LNG108 protein scattergram in serum

